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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,501	04/22/2002	Hiroyuki Saito	053466-0325	9449

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EXAMINER	
BURKHART, MICHAEL D	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,501	SAITO ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *1-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/02, 6/02, 8/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 9-53 in the reply filed on 10/8/2004 is acknowledged. The traversal is on the ground(s) that there is no undue burden to examine all the claims, and that the claims possess unity of invention. This is not found persuasive because, under 371 restriction rules, examination burden is not a consideration and the restriction requirement clearly establishes lack of unity between the two groups. As detailed in the restriction requirement, the special technical feature of Group I is an animal having an implanted cell that encodes human tissue factor, a feature not found in Group II. The special technical feature of Group II is an antibody to human tissue factor, a feature not found in Group I.

The requirement is still deemed proper and is therefore made FINAL.

Priority

This application, filed 4/22/2002 claims priority to PCT/JP00/06802, filed 9/29/2000, therefore the instant invention has been granted a priority date of 9/29/2000.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

Claims 14 and 24 are objected to because of the following informalities: "chimereic" should be spelled "chimeric". Appropriate correction is required.

Applicant is advised that should claim 12 be found allowable, claim 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof, should claim 22 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof, and should claim 43 be found allowable, claim 52 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 15 be found allowable, claims 33, 42, and 51 will be objected to under 37 CFR 1.75 as being a substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14-15, 24, 32-33, 41-42, and 50-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 24, 32, 41, and 50 recite the limitation "said altered antibody" in line 2. There is insufficient antecedent basis for this limitation in the claim. This rejection affects all dependent claims.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The instant invention is drawn to therapeutic agents for disease, of which the only disclosed ingredient is an antibody to human tissue factor. Therefore, disclosure of such antibodies is considered anticipatory of the claimed therapeutic agent.

Claims 9, 11-14, 16-18, 20-27, 29-32, 34-36, 38-41, 43-45, 47-50, and 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated by del Zoppo (U.S. Patent 5,879,677, issued March 9, 1999). The instant claims are drawn to an antibody specific for human tissue factor. The antibody (Ab) may be: monoclonal; recombinant; altered; chimeric or humanized; modified; or an Ab fragment such as Fab, F(ab')2, Fv, or a single chain Fv (scFv). del Zoppo discloses human tissue factor (TF) monoclonal antibodies (MAbs) for treatment of unwanted blood coagulation (claims 1-3 and column 4, lines 48-61). The MAbs may be modified into active portions, such as Fab, Fab', F(ab')2, or Fv portions (column 4, lines 19-29). The antibodies may be altered to be chimeric or

humanized by replacement of the constant regions with that of the host species (i.e., humans, paragraph bridging columns 6 and 7).

Claims 9, 11-14, 16-18, 20-27, 29-32, 34-36, 38-41, 43-45, 47-50, and 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Huang et al (Science, 1997, cited by applicants). The claims are described above. Huang et al teach a bispecific, chimeric antibody comprising the Fab arm of the B21-2 antibody linked to the Fab arm of the 10H10 antibody, specific for human tissue factor (see paragraph bridging pages 547 and 548).

Claims 9-11, 18-20, 27-29, 36-38, and 45-47, are rejected under 35 U.S.C. 102(b) as being anticipated by Randolph et al (Blood, 1998, cited by applicants). The claims are drawn to an antibody specific for human tissue factor that may be monoclonal or polyclonal. Randolph et al teach a panel of anti-TF monoclonal antibodies (Materials and Methods, page 4167, second column under *Antibodies and recombinant proteins*) that were tested for their effect, *inter alia*, on reverse transendothelial migration of mononuclear phagocytes (Fig. 2, pg. 4171). Goat anti-TF polyclonal antibody was available commercially from American Diagnostics (Materials and Methods, pg. 4168, first column, lines 3-4).

Claims 9, 11-16, 18, 20-25, 27, 29-34, 36, 38-43, 45, and 47-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Sato et al (U.S. Patent 6,677,436, issued 1/13/2004).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims are as described above, except that the humanized antibody may be of the version b-b, i-b, or i-b2. The lower-case letters designate the version (sequence variants) of the heavy (H) and light (L) chains of the variable (V) region of the humanized MAb. In this system the first letter designates the heavy chain version, and the second the light chain, so i-b would have the i variant of the heavy chain and the b variant of the light chain. Sato et al teach human/mouse chimeric, humanized antibodies against human tissue factor (abstract, column 4). The authors also disclose humanized antibodies of the structures b-b (column 51, lines 20-34), i-b (column 52, lines 17-34), and i-b2 (column 52, lines 58-67). Figures 31-34 contain all three of these humanized MAbs.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
Art Unit 1636

DAVID GUZO
PRIMARY EXAMINER